FDA CENTER FOR DRUG EVALUATION AND RESEARCH
DIVISION OF ANESTHESIA AND ANALGESIA PRODUCTS

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety & Risk Management Advisory Committee
April 22, 2010
NDA 22-451 for ACUROX, an Immediate-Release Formulation of Oxycodone & Niacin

Questions to the Committee

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1. Discuss what constitutes an adequate degree of abuse-deterrence to warrant description in the product's label and the potential implications regarding overstating these effects.

2. Based on the results of the studies assessing the effects of niacin on drug liking:
   (a) Were the studies conducted appropriately to assess the effects of niacin on the abuse liability of oxycodone?

   (b) If not, what changes should be made to the studies?

   (c) Is the presence of niacin in the formulation a potentially effective deterrent?

   (d) Are the effects of ingesting the product with food or aspirin/NSAIDS sufficient to reduce the deterrent effect of niacin to a level that is no longer clinically relevant?

3. Was the degree of flushing seen in patients treated in the clinical trials acceptable for this product with properties targeted at deterring misuse and abuse?

4. Please vote on whether Acurox should be approved for the indication of the treatment of moderate to severe pain taking into consideration your conclusion regarding the deterrent effect of the niacin, as well as the potential deterrent effects of the other features specific to the Acurox formulation of oxycodone.